CHAPTER 9. DOD/FDA SHELF LIFE EXTENSION PROGRAM (SLEP)

9-1. BACKGROUND

a. The DoD/FDA Shelf Life Extension Program is a key component of the Medical Readiness Strategic Plan (MRSP) as developed by the Office of the Secretary of Defense for Health Affairs and the Military Medical Departments in response to Congressional concern over the conservation of military medical resources. The program's focus is to defer drug replacement costs for **date-sensitive, pre-positioned stocks** by extending their useful life. The following organizations participate in the program:

The Food and Drug Administration (FDA)
The Defense Medical Standardization Board (DMSB)
Army
Navy
Air Force
Marine Corps
Defense Supply Center-Philadelphia (DSCP)
The Department of Homeland Security's Strategic National Stockpile (SNS)
The Veterans Administration Emergency Preparedness Program

b. The FDA evaluates selected materiel for shelf-life extension by testing samples submitted from the Shelf-Life Extension Program (SLEP) Participants. The Defense Medical Standardization Board (DMSB) coordinates the program and acts as the single interface between the SLEP Participant and the FDA. The SLEP Participant funds the program, manages their portions of the program, and receives the benefit of deferred materiel replacement costs. SLEP assures only safe and effective drugs are provided to personnel during war or other contingencies.

9-2. TESTING CRITERIA

a. The FDA is the independent evaluator and proponent for quality control of medical materiel, performing all required testing of items entered into the DoD/FDA SLEP. The FDA uses the U.S. Pharmacopoeia or the original manufacturer's test data on each item to establish a protocol for testing. Accelerated testing (also called stress testing) is the method used most often to predict the extension period. The accelerated testing protocols are designed to increase the rate of chemical or physical degradation of the drug substance by using exaggerated storage conditions. Each item is "stressed" (placed in chamber which maintains a temperature of 50 degrees centigrade and 75% humidity) for 60 days. The potency of the stressed samples is compared with the standard for each item, and using the comparison, the FDA estimates the extendable life of the product. The FDA testing process, from the time the DMSB presents the project's candidate list until the results are received by the DMSB, requires approximately six months.

b. The FDA will not test all items presented to them as program candidates. The FDA's Center for Biologics Research (CBER) has never permitted the testing of any biological products (vaccines, toxoids, serums, blood products, etc.) in the SLEP. In addition, nutritional products and products with a history of poor performance in the SLEP testing process (e.g., water purification tablets, amoxicillin with clavulanate potassium and Mefloquine®) are not accepted for testing nor are items where the testing is time and/or cost prohibitive.

c. The testing conducted by the FDA is comprehensive and scientifically sound. The FDA bases their expiration date extensions on conservative estimates of the useful life of the product as substantiated by the test results. Statistical methods are employed to predict when each product would be expected to breach the acceptable potency specification, and a date less than that expected breach is chosen. The FDA grants the extensions for all SLEP Participates having the materiel as specified by lot number, expiration date, and manufacturer that has been stored under appropriate conditions. Testing of SLEP products is an ongoing process. Annually or biannually the materiel is retested to confirm extended dating (or permitted further extensions).

This is a mandatory requirement for all materiel remaining in the SLEP. Products that fail testing at any time will be destroyed. Products that are not tested or do not receive additional extensions are destroyed upon reaching their final expiration date.

9-3. THE SLEP PROCESS

a. All pre-positioned stocks should be rotated when possible; however, quantities often exceed normal requirements. In June 2005, the DoD/FDA Shelf Life Extension Program moved from an Access database that could only be accessed by users on Ft Detrick to a Web-based Oracle database that may be accessed by all users of the SLEP system through the internet. The system requires all Army users **to enter their on-hand inventory of MCDM medical materiel** and anti-malaria medicals **as soon as they receive those items**. The lots are loaded into the system under different categories as shown in Table 9-1. You are required to update your inventory once a quarter. You will be sent an email at the end of each month for each lot that has not been updated in the last 90 days. Efforts are currently being worked to provide an automatic feed from your materiel accounting systems, e.g., DMLSS-AM, into SLEP for stockpiled items. This will free you from entering the items into DMLSS and SLEP; you will only have to enter it in to DMLSS. You still will have to use SLEP to view messages, process sample requests, check for lot dispositions, and process receipt of labels. OTSG and USAMMA use the data in SLEP for budgeting, reporting, and management of MCDM and anti-malaria materiel.

b. On a quarterly basis a list is generated of all materiel that is going to expire in the next 180 days. This list is scrubbed against the total on-hand quantities and the original expiration date of the item. Ten (10) years is the maximum time the FDA will extend an item from its original manufacturer's expiration date. Some items many not be extended for that many years, e.g., silver sulfadiazine cream which turns brown after 5 years of testing and diazepam with builds up impurities after 7 years. The FDA and the Services require that there be at least $10,000.00 of a lot still on hand to test; otherwise, testing is not cost effective. You, as the Army SLEP User at the stockpile location, are critical to the program. You have been tasked by USAMMA or USAMEDCOM to ensure that all stock is identified correctly in the SLEP website. There are exceptions to the above rules when an item is in short supply and required for possible/actual event/operation.

c. Once a specific lot has been identified as a possible test candidate, it is marked in the system with a Lot Status: **ADD TO TEST**. At this time, the FDA gets the list of all possible test candidates for the next 180 days and requests samples through the automated system to the Army SLEP POC. The Army SLEP POC will notify one of the Activities that they are to provide "xxx" amount of materiel (by lot and NSN) to the FDA and where to ship it. How to package and ship samples is in SLEP message 2005-0057 (available on the SLEP Web site at https://slep.dmsbfda.army.mil). Sometimes the FDA will only request a copy of the label on the product. This is normally when the manufacturer produced several lots from one batch and is usually a one-time request in the testing history of the lot. The FDA requires receipt of requested samples within 30 days of the notice. If a lot's samples are not received within 30 days, the item is dropped from the project and testing on the samples that were received begins. Timely submission of samples is critical to successful completion of a project. The SLEP user must also enter into the SLEP Database - as a minimum - the date the sample is shipped and the mode of shipment (e.g., FEDEX, USPS, DHL).

d. When the FDA has received all the samples for new testing, or it has been 30 days since the request for samples was sent, the FDA assigns a project number and sends the list by lot numbers of products that will be tested to DMSB. DMSB enters this information into the SLEP database. A SLEP New Test message is prepared and sent via email to all users of the SLEP system. The list of the lots being tested in a project can also be checked by going to the Reports and Queries section of the Web Site (https://slep.dmsbfda.army.mil) and selecting FDA Projects.

e. Upon completion of testing, the FDA forwards the results to the DMSB who inputs them into the SLEP database. A SLEP-Test Results message is prepared and sent via email to all users of the SLEP system. Any SLEP participating activity having those items by lot number may extend that materiel to the new expiration date, but only if that materiel has been properly stored

in accordance with the manufacturer's specifications. Once a product has been tested, it will be re-tested biannually or annually until the product fails testing or stocks are depleted.

f. The direction of the program has changed since its inception. The switch from a large DoD depot supply system to one supported predominantly by prime vendor suppliers and just-in-time deliveries for day-to-day requirements has refocused the program to pre-positioned stockpiles of Chemical Biological Radiological Nuclear (CBRN), Pandemic and anti-malaria materiel. The prime vendor system has reduced the need for centrally controlled warehousing of drugs therefore reducing the pool of products that are eligible for testing. Additionally, all medical facilities in DoD have the ability to return goods for credit or replacement. The Return Goods Program allows replacement of expiring products with little or no cost to the facility.

g. The DoD enjoys a high rate of success with the SLEP because only products known to have a high probability of being extended are included in test projects. Due to the DoD's history and knowledge gained with the program, items with low probability of being extended are not included unless there is a compelling reason for the testing.

Table 9-1. SHELF LIFE EXTENSION PROGRAM CATEGORIES FOR ARMY MATERIEL

NAME OF PROGRAM	PROJECT CODE FOR DMLSS	ASSEMBLY CODE FOR DMLSS	SLEP CATEGORY	OWNED/ FUNDED BY	RELEASED BY
Medical Chemical, Biological, Radiological, and Nuclear Defense Materiel (MCDM)	DH1	YMBC	CBRN	OTSG NBC Readiness	OTSG Health Care Operations
Potency & Dated (P&D) MCDM components of the MES LIN M23673	DH5	CPTS	CBRN	OTSG NBC Readiness	OTSG Health Care Operations
Army Emergency First Responder Program (AEFRP) CBRN Pharmaceutical Countermeasures (CPCs)	DH3	YAFR	Installation	ARMY JP Guardian	Installation Commander
Installation Protection Program (IPP) CBRN Pharmaceutical Countermeasures (CPCs)	DH3	YIPP	Installation	DoD JP Guardian	Installation Commander
DOD Nuclear Pharma-ceutical Countermeasures (Prussian Blue)		YBLU	HA	DOD Health Affairs	TBD
MCDM in SMART Teams	DH2		Contingency	USAMEDCOM	OTSG Health Care Operations
Army Prepositioned Stocks (APS)	Multiple	Multiple	War Reserve	Army G-4	OTSG Health Care Operations
Unit Deployment Packages (UDP)	Multiple	Multiple	Retail	OTSG Logistics	OTSG Health Care Operations
Antibiotics		YABX	HA	DOD Health Affairs	Combatant Commander (COCOM)
Anti-Virals		YAV1	HA	DOD Health Affairs	HA

9-4. LABELING REQUIREMENTS AND GUIDANCE

a. The FDA requires that product be labeled and relabeled in accordance with the Food, Drug and Cosmetic Act of 1938 (or subsequent amendments) or the Food and Drug Modernization Act of 1997. Products not relabeled in accordance with these laws or FDA regulations are considered misbranded if they are sold, distributed, or dispensed and are in violation of these Acts.

b. The FDA Center for Drugs (CDER) Compliance Office recommends for the DoD, that the extended product be relabeled with the lot number, new expiration date, and FDA project number. The new sticker does not have to be the same font and color as the old label. However, the new sticker must not obscure the writing on the original label and the new sticker must be legible. In addition, the sticker must adhere to the old label in such a way that if it was peeled off, what was underneath it would also peel off. It is not necessary nor is it advised to remove the original label on a product and put on a new label. The FDA does not want the original product label removed. Putting a new label on the product will require approval by the FDA Compliance Office. The intent of this is to instill confidence in the ultimate user that the products they are given or administered are of high quality and safety and will work effectively as expected

c. The FDA has authorized a deferral of the requirement to have every individual unit of issue relabeled, but only while the materiel is maintained under centralized SLEP participants' control. This was requested in order to reduce the cost for multiple relabeling efforts, as SLEP products may be extended multiple times prior to being issued to individual service members. The FDA will permit SLEP Participants to label only the outer cartons of products with the updated information so long as they remain in centralized storage, control, and management. This materiel **must be relabeled completely**, down to the individual units of issue, **before being distributed/issued to activities or individuals.**

d. The printing and distribution of the extension labels is being automated in the SLEP. This feature will be fully operationally in the 3rd Quarter, 2007. When the FDA sends the results of a Shelf Life Extension Project to the DMSB an order for labels will be generated. Activities will only receive labels if:

- They have updated their inventory in SLEP in the last 6 months
- They have updated their address in the SLEP system to a FEDEX address or a full US Postal address.
- A FEDEX address must include a street and building number, city, state, and zip code.
- A US Postal Address must include a City, state and zip code. For non-US address, include the country.

e. Activities will receive an email when the order has been placed for their labels. Activities will comply with the SLEP message instructions and will acknowledge receipt for the labels in the SLEP database when they are received.

9-5. WEBSITE INFORMATION

a. On-line access is now available to the DOD/FDA Shelf Life Extension Program. Registration is required for access to the site. The site is: https://slep.dmsbfda.army.mil. The site features the SLEP messages, interactive query, and quantity reporting capability for SLEP eligible materiel.

b. SLEP message before June 2005 are at the USAMMA's home page at http://www.usamma.army.mil/. Select the DOD MMCQ Messages box.

9-6. ADDITIONAL INFORMATION

For additional information on this subject, contact:

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